UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/753,461	01/09/2004	Justin Goshgarian	PA1776 US (1737.2770000)	6424

28390 7590 06/14/2007

MEDTRONIC VASCULAR, INC.
IP LEGAL DEPARTMENT
3576 UNOCAL PLACE
SANTA ROSA, CA 95403

EXAMINER	
NEAL, TIMOTHY J	

ART UNIT	PAPER NUMBER
3731	

NOTIFICATION DATE	DELIVERY MODE
06/14/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

rs.vasciplegal@medtronic.com

Office Action Summary	Application No.	Applicant(s)	
	10/753,461	GOSHGARIAN, JUSTIN	
	Examiner	Art Unit	
	Timothy J. Neal	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 March 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is in response to the amendments received on 3/29/2007.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 13, 17-19, 24, 25, 29, 30, 33, and 34 are rejected under 35 U.S.C. 102(e) as being anticipated by Cottone et al. (US 2004/0093058.

Cottone discloses:

13. An ostium stent system, comprising: a balloon catheter (Item 530), wherein the balloon catheter includes a balloon mounted on a distal portion of the balloon catheter (Item 530); and a stent mounted on the balloon (Item 100), the stent including: a tubular body having a longitudinal axis, a proximal end and a distal end, wherein the tubular body is constructed from a first material and is expanded by inflation of the balloon (Item 100); at least one flaring member weld-connected to the proximal end of said tubular body, wherein said at least one flaring member is made from a second material different

than the first material and is self expandable (Item 200); and a retaining structure covering only said at least one flaring member, wherein the removal of said retaining structure results in the expanded configuration of said at least one flaring member (Item 520).

17. The ostium stent system of claim 13, wherein said second material is from an elastic material (Paragraph 22).

18. The ostium stent system of claim 13, wherein said first material is nitinol (Paragraph 22).

19. The ostium stent system of claim 13, wherein said at least one flaring member is comprised of a short segment and a long segment, wherein said at least one flaring member is attached to the proximal end of said tubular body with the short segment and the long segment both generally parallel to the longitudinal axis of said tubular body in an unexpanded configuration (Fig 5), and wherein the short segment of said at least one flaring member remains generally parallel to the longitudinal axis of said tubular body in an expanded configuration (Fig 12), and the long segment of said at least one flaring member becomes generally perpendicular to the longitudinal axis of said tubular body in the expanded configuration (Fig 12).

24. An ostium stent system, comprising: a balloon catheter (Item 530), wherein the

balloon catheter includes a balloon mounted on a distal portion of the balloon catheter (Item 530); and a stent (Item 100) mounted on the balloon, the stent including: a tubular body having a longitudinal axis, a proximal end and a distal end, said tubular body being constructed from a first material, wherein the tubular body is expanded by inflation of the balloon (Item 100); and at least one flaring member weld-connected to the proximal end of said tubular body, said at least one flaring member being made from a second material different than said first material, wherein said at least one flaring member is self expandable (Item 200).

25. The ostium stent system of claim 24 further comprising a retaining structure covering only said at least one flaring member, wherein the removal of said retaining structure results in the expanded configuration of said at least one flaring member (Item 520).

29. The ostium stent system of claim 24, wherein said second material is nitinol (Paragraph 22).

30. The ostium stent system of claim 24, wherein said at least one flaring member is comprised of a short segment and a long segment, wherein said at least one flaring member is attached to the proximal end of said tubular body with the short segment and the long segment both generally parallel to the longitudinal axis of said tubular body in an unexpanded configuration (Fig 5), and wherein the short segment of said at least

one flaring member remains generally parallel to the longitudinal axis of said tubular body in an expanded configuration (Fig 12), and the long segment of said at least one flaring member becomes generally perpendicular to the longitudinal axis of said tubular body in the expanded configuration (Fig 12).

33. The ostium stent system of claim 24, wherein the stent is a multiple module prosthesis and the multiple modules are fixed together (Fig 4B).

34. The ostium stent system of claim 33, wherein the multiple modules are fixed together by welds (Product by process, considered but given no patentable weight).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cottone '058.

Cottone discloses the invention substantially as claimed as stated above. The Examiner considers independent claims 13 and 24 to be written such that welding and not necessarily a weld connect the flaring member and tubular body. This limitation is considered to be a product-by-process limitation and thus given little to no patentable

weight. However, the Examiner is also rejecting those claims with an obviousness rejection to clearly address the patentability of the claims. The Examiner considers weld-connecting stent portions to be old and well known in the art. Welding is a known attachment means that provides a strong joint. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the connecting means of Cottone to include welding. Such a modification would provide a strong attachment for the two sections. Cottone's membrane material is susceptible to shearing forces. If the material were torn during entry, the portions would separate and cause a number of problems. Welding is stronger and not as likely to shear or tear during entry thus avoiding any problems associated with separation of the elements.

Cottone discloses the invention substantially as claimed as stated above. Cottone does not explicitly disclose the stent comprising the cobalt-chrome alloy MP35N and the first material being stainless steel. Cottone does disclose the tubular body being balloon expandable. The Examiner considers these alloys to be well known in the art for use with stents. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Cottone's stent to include the cobalt-chrome alloy or stainless steel. MP35N and stainless steel offer good biocompatibility and expansion characteristics.

Cottone also does not explicitly disclose the lengths associated with the flaring member. However, the Examiner considers it to be within the purview of a person having ordinary skill in the art to adjust Cottone's flared portion to any desired length. Furthermore, Figure 4B shows the general relation between the short segment and the

long segment of the flaring member. In this drawing, the relative lengths between the two segments are substantially equivalent to the claimed lengths. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Cottone's segments to the claim's lengths. Such a modification would provide desirable length characteristics for a variety of differently sized lumens. Furthermore, there is a need for the long, perpendicular segments to be significantly longer than the short segments so that the device will be able to maintain its location. If the segments are too short, the segments will not maintain their proper expanded position, and the device will be susceptible to movement.

Response to Arguments

Applicant's arguments with respect to claims 1-34 have been considered but are moot in view of the new ground(s) of rejection.

The Applicant has argued that Cottone does not disclose the two sections being welded together and that there would be no motivation to replace the connecting membrane with a weld connection. The Examiner respectfully disagrees. The Examiner considers welding to be a well-known technique in the art for attaching two elements. Welding provides a strong connection means so that the elements do not separate during entry or deployment. The Examiner notes the art cited below as examples of stents with welding, including welding between different materials. The Examiner also notes that welding is essentially a process of connecting elements. Although welding does create weld points, it is not generally considered to provide a

distinct structure. Welding is widely considered in the art as one form of connection that is known to a person having ordinary skill in the art. Therefore, the claims can be interpreted as product-by-process claims having little to no patentable weight. The Examiner has provided an anticipation and obviousness rejection in an attempt to avoid further arguments regarding product-by-process language. Furthermore, the Examiner points to the Applicant's disclosure Paragraph 48 in which the Applicant suggests that other methods of connecting the tubular body and flaring portion may be used. This suggests to the Examiner that welding is not the only means to achieve the desired results of the Applicant's invention. Basically, welding is not critical to the invention. For at least these reasons, the Examiner considers the amendments to be anticipated and/or rendered obvious by the prior art as stated above.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Birdsall et al. (US 5,817,152), Dinh et al. (US 6,019,789), and Globerman (US 2005/0288769) disclose a stent with multiple sections connected to each other by welding. Ischinger (US 6,146,417) discloses connecting different materials by welding.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy J. Neal whose telephone number is (571) 272-0625. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TJN

(JACKIE) TAN-UYEN HO
PRIMARY EXAMINER
6/18/07